



The Commonwealth of Massachusetts  
Executive Office of Health and Human Services  
Department of Public Health  
Division of Health Care Quality  
10 West Street, Boston, MA 02111-1212  
617-753-8000

MITT ROMNEY  
GOVERNOR

KERRY HEALEY  
LIEUTENANT GOVERNOR

RONALD PRESTON  
SECRETARY

CHRISTINE C. FERGUSON  
COMMISSIONER

TO: Commissioner Ferguson and Members of the Public Health Council

THROUGH: Nancy Ridley, Assistant Commissioner  
Bureau of Health Quality Management

FROM: Paul Dreyer, Director  
Division of Health Care Quality

DATE: November 18, 2003 (Issued November 12, 2003)

RE: Informational Briefing on Proposed Amendments to the Hospital  
Licensure Regulations (105 CMR 130.000) Regarding the Designation  
of Primary Stroke Services

Over the past several months, the Department has been working with clinicians, hospitals, and advocates to develop standards for designating Primary Stroke Services in hospitals that are equipped to rapidly triage and treat patients presenting with symptoms of acute stroke. These standards for voluntary designation are based on the nationally recognized consensus position outlined in "Recommendations for the Establishment of Primary Stroke Centers," which appeared in JAMA, June 21, 2000, Vol.283, No.23, pages 3102-3109.

#### Background

Each year over 3500 Massachusetts citizens die from stroke. Stroke is the third leading cause of death in Massachusetts and a leading cause of disability. Stroke is a type of cardiovascular disease that affects the arteries leading to and within the brain. There are two major types of acute stroke. Acute hemorrhagic stroke occurs when a blood vessel, which carries oxygen and nutrients to the brain, ruptures and causes bleeding into or around the brain. Acute ischemic stroke occurs when a blood vessel to the brain is blocked by a clot. An estimated eighty percent of strokes are ischemic. Historically,

no effective treatment has been available for acute ischemic stroke. Clinical trials have established thrombolytic therapy as an effective treatment if administered within limited time parameters. Based on these clinical trials, the Food and Drug Administration approved the use of tissue-type plasminogen activator, a thrombolytic agent also known as t-PA, for patients with acute ischemic stroke if given within three hours of symptom onset. However, less than five percent of people with acute ischemic stroke receive thrombolytic agents within the recommended time frames. The American Heart Association and other clinical standard setting entities have recommended that Primary Stroke Services be established to ensure that clinically eligible patients are afforded the opportunity to receive this definitive care.

### Proposed Amendments to the Hospital Licensure Regulations

With the goal of improving the care and outcomes of acute ischemic stroke patients, the Department has drafted the attached proposed amendments to the hospital licensure regulations to establish standards for Primary Stroke Services. A hospital providing licensed emergency services may apply for designation. The standards include the following hospital requirements:

- 1) creation of an Acute Stroke Team, with a physician director who has training and expertise in cerebrovascular disease,
- 2) development and implementation of written care protocols,
- 3) availability of the service 24 hours per day, seven days a week,
- 4) development and implementation of effective communication with Emergency Medical Service personnel in the pre-hospital setting during the transportation of a patient with symptoms of acute stroke,
- 5) rapid availability of neuroimaging and other imaging, electrocardiogram, laboratory and neurosurgical services,
- 6) continuing health professional education,
- 7) development and implementation of quality assessment and improvement programs, and
- 8) data collection, with submission of select data to a data center approved by the Department.

Upon promulgation of the Primary Stroke Service Licensure Regulations, the Department will issue an advisory bulletin establishing the time targets, the data set and data centers referenced in the regulations.

The Department will release the proposed amendments for public hearing and comment and return to the Council with a final recommendation.